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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,264	12/03/2001	Laurie H. Glimcher	HUI-040CP	2529
959	7590	10/14/2005	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			OUSPENSKI, ILIA I	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/008,264

Applicant(s)

GLIMCHER ET AL.

Examiner

ILIA OUSPENSKI

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 50-58 and 60-65 is/are pending in the application.
- 4a) Of the above claim(s) 3, 5, 7, 52 and 56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6, 8-12, 50, 51, 53-55, 57, 58 and 60-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

soo

Continuation of Attachment(s) 6). Other: Sequence Error Report.

DETAILED ACTION

1. Applicant's amendment/remarks, filed 07/22/2005, are acknowledged.

Claim 59 has been cancelled.

Claims 13 – 49 have been cancelled previously.

Claims 1, 3 – 8, and 50 – 58 have been amended.

Claims 60 – 65 have been added.

Claims 1 – 12, 50 – 58, and 60 – 65 are pending.

Claims 3, 5, 7, 52, and 56 have been withdrawn from consideration by the Examiner as being drawn to nonelected inventions.

2. Applicant's election with traverse of Group I of the re-drafted Restriction Requirement set forth in the previous Office Action, in the reply filed on 07/22/2005 is acknowledged. The traversal is on the grounds that the murine and human T-bet protein sequences are related, and their searches would be coextensive. This is not found persuasive because each sequence requires a separate search. It is an undue burden to search more than one invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 4, 6, 8 – 12, 50, 51, 53 – 55, 57 – 58, and 60 – 65, as they read on the elected invention of nucleic acids encoding human T-bet protein, are under consideration in the instant application.

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3. This Office Action will be in response to applicant's arguments, filed 07/22/2005.

The rejections of record can be found in the previous Office Action, mailed 01/24/2005.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

It is noted that New Grounds of Rejection are set forth herein.

4. Sequence compliance: Applicant's provision of a substitute CRF is acknowledged. However, this submission fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Sequence Listing Error Report.

Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) in response to this Office Action.

5. Priority: In view of the evidence presented by Applicant, the provisional application USSN 60/137,085 appears to provide adequate support under 35 U.S.C. 112 for subject matter claimed in the instant application, including claim 50.

6. The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth supra.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 50, 60, and 64 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 50 and 64 are indefinite in the recitation of "initiation of Th1 cell differentiation of Thp cells and Th2 cells," because it is unclear whether the intended meaning is differentiation of Th1 cells into Thp and Th2 cells or differentiation of Thp and Th2 cells into Th1 cells. It is noted that for examination purposes, the latter interpretation is assumed.

B. Claim 60 is indefinite in the recitation of "prosthetic group," because the recitation lacks antecedent basis in the base claim 57. According to Webster's New World Dictionary (Third College Edition, 1988, page 1080), "prosthetic" means, as applied to chemical groups, "designating or of any of a number of nonprotein compounds when combined chemically with a protein molecule." Since claim 60 recites "the nucleic acid molecule of claim 57," rather than a protein molecule, the recitation of "prosthetic group" lacks antecedent basis.

C. Claim 64 is indefinite in the recitation of "wherein the Th1-associated cytokine is ... IL-2," because the recitation lacks antecedent basis in the base claim 50, in view of the instant specification on page 14. Claim 50 recites induction of Th1-associated cytokine production under the influence of T-bet polypeptide, while the instant specification discloses at page 14, lines 33 – 34, that T-bet leads to repression of IL-2 production. Therefore, recitation of IL-2 in claim 64 is inconsistent with the recitation of claim 50, and as such, lacks antecedent basis.

Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

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Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 60 is rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicant's amendment asserts that no New Matter has been added and points to the specification at page 34, lines 34 – 36 for support for the newly added claim. However, the specification does not appear to provide an adequate written description of the newly added limitations.

The specification at page 34, lines 34 – 36 discloses anti-T-bet antibody labeled with a detectable substance, such as an enzyme, prosthetic group, fluorescent material, luminescent material, or a radioactive material. The specification does not appear to disclose a nucleic acid molecule labeled with such detectable substances, and as such, does not provide an adequate written description of the claimed limitations.

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the

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specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

11. Claim Rejection, provisional obviousness-type Double Patenting: Applicant's submission that upon an indication of allowability in this or the related application Applicant will consider filing a terminal disclaimer is acknowledged.

In the absence of such filing, ***the rejection of record is maintained for the reasons of record***, as it applies to the amended and newly added claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Conclusion: no claim is allowed.

The claims appear to be free of prior art.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI

Patent Examiner

Art Unit 1644

September 27, 2005

Phillip Gambel
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PRIMARY EXAMINER
TECH CENTER 1600
10/11/05